

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Application Number	10/829,618
Filing Date	4/20/2004
Inventor(s)	Dudley et al.
Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

**U.S. PATENT DOCUMENTS**

Exam. Initial	No.	Document No.	Issue/Publication Date	Applicant(s)
	1.	4615697	10/7/1986	Robinson
	2.	4919937	4/24/1990	Mauvais-Jarvis et al.
	3.	3164520	1/5/1965	Huber
	4.	4496455	1/29/1985	Linder et al.
	5.	5769274	6/23/1998	Behar
	6.	5926953	7/27/1999	Behar

**FOREIGN PATENT DOCUMENTS**

Exam Initial	No.	Document No.	Publication Date	Country
	7.	WO9637201	11/28/1996	PCT
	8.	WO9830198	7/16/1998	PCT

**OTHER DOCUMENTS (Non-patent literature)**

Exam. Initial	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	9.	"ALZA introduces TESTODERM TTS for testosterone deficiency - survey finds key role of testosterone unknown to most men." Alza. March 11, 1998. <a href="http://www.alza.com/print/pr_957321395">http://www.alza.com/print/pr_957321395</a> (accessed 11/15/2004).

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	10.	"Androderm Watson Pharmaceuticals reacquires U.S. and Canadian marketing rights to A(R) testosterone transdermal system." Watson Pharmaceuticals Inc. May 17, 1999.
	11.	"Cellegy Pharmaceuticals Initiates Phase III Clinical Trial Using Transdermal Testosterone Gel." PR Newswire. March 29, 2000.
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	16.	"Unimed Pharmaceuticals Completes Clinical Trial Enrollment for First Topical Testosterone Replacement Gel." Press Release. May 28, 1998.
	17.	"Unimed Pharmaceuticals Licenses Testosterone Products." PR Newswire. August 14, 1995.
	18.	"Unimed Pharmaceuticals Licenses Two Testosterone Products." Pharma Marketletter. August 21, 1995.
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		Research Initiatives." Marcel Dekker: New York (1990). Ch. 10.
	22.	Kim et al. "Preparation and evaluation of Eudragit gels. v. rectal gel preparations for sustained release and avoidance of first-pass metabolism of lidocaine." Chem. Pharm. Bull. 50(10): 2800-2804 (1992).
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	26.	Mollgaard et al. "Permeation of estradiol through the skin-effect of vehicles." Int'l J. Pharm. 15: 185-197 (1983).
	27.	O'Carroll et al. "Androgens, behaviour and nocturnal erection in hypogonadal men: the effects of varying the replacement dose." Clin. Endocrinol. 23: 527-538 (1985).
	28.	Pavlov. "Indications and technique of intra-articular administration of hydrocortisone to patients with infectious nonspecific polyarthritis." Soviet Medicine (1964). [in Russian with English Abstract]
	29.	Sauvez et al. "Cutaneously applied 4-hydroxytamoxifen is not carcinogenic in female rats." Carcinogenesis. 20(5): 843-850 (1999)
	30.	Szadurski. "The application of a galvanic penetration test for the rapid determination of skin resistance to bases." Przegląd dermatologiczny [Dermatological Review]. 55(1):20-3 (1968).
	31.	Tenover. "Male Hormone Replacement Therapy Including 'Andropause.'" Endocrinol. Metab. Clin. North. Am. 27(4): 969-987 (1998)

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	32.	Thompson, ed. "The Concise Oxford Dictionary." 9th ed. Oxford: Oxford University Press, 1995, pp. 1014.
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**OFFICE ACTIONS AND RESPONSES IN CO-PENDING U.S. PATENT APPLICATIONS**

Exam Initial	No.	Application Serial No.	Date of Office Action or Response
	35.	10/829618	12-30-2010 Final Rejection

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**U.S. PATENT DOCUMENTS (Referenced in Litigation)**

Exam. Initial.	No.	Document No.	Issue/Publication Date	Applicant(s)
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	37.	5952000	7/21/1997	Venkateshwaran (previously cited in IDS filed 11/12/2010(2))
	38.	5686112	11/11/1997	Liedtke (previously cited in IDS filed 11/12/2010(2))
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	43.	EP 0581587	2/2/1994	EPC (previously cited in IDS filed 11/12/2010(2))
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### OTHER DOCUMENTS (Non-patent Literature- Referenced in Litigation)

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	48.	De Lignieres et al., Treatment of Male Hypogonadism by Topical Administration of Androgens. In: Mauvais-Jarvis et al. Eds. Percutaneous Absorption of Steroids, pp. 273-283 (1980) (previously cited in IDS filed 11/12/2010(2))
	49.	Chemistry: The Central Science, 2d Edition, pp. 75-76, 84-86, 348-349 (1981)
	50.	BARRY, Dermatological Formulations, Percutaneous Absorption, Marcel Dekker (1983) (previously cited in IDS filed 11/12/2010(2))
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	52.	PENA, Topical Drug Delivery Formulations, ed. Osborne and Amann, Vol. 42, pp. 381-388 (1990) (previously cited in IDS filed 11/12/2010(2))
	53.	SURBER et al., Optimization of Topical Therapy: Partitioning of Drugs into Stratum Corneum, Pharmaceutical Res., Vol. 7(12), pp. 1320-1324 (1990) (previously cited in IDS filed 11/12/2010(2))
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	55.	De Lignieres, Transdermal Dihydrotestosterone Treatment of Andropause, Annals of Medicine 25: 235-241, 1993 (previously cited in IDS filed 11/12/2010(2))
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	60.	The United States Pharmacopeia, "alcohol": pp. 42-43 (1995)
	61.	Smith et al., Percutaneous Penetration Enhancers, pp. 21-28 (1995)
	62.	BOCKSERMAN, Med. Plastics and Biomaterials Mag., pp. 26-33 (July 1996) (previously cited in IDS filed 11/12/2010(2))
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	71.	Wang, et al., Pharmacokinetics Of Transdermal Testosterone Gel In Hypogonadal Men, Abstract P2-51, 80th Annual Meeting of the Endocrine Society, New Orleans, Louisiana, June 1998 (ENDO '98) (previously cited in IDS filed 11/12/2010(2))
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	83.	Wang et al., Male Reproductive Function, Kluwer Acad. Publ. (May 1999). Table of Contents.
	84.	Biotech Business, "Unimed Submits NDA to Market "Androgel" Testosterone Gel" (June 1999)
	85.	"Products Filed For Approval: Androgel - Unimed Applies for FDA Approval for Androgel Gel for the Treatment of Low Testosterone Levels in Hypogonadal Men," R&D Directions 5(7) (July 1999)
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	92.	Swerdloff RS, et al., "Long-term pharmacokinetics of transdermal testosterone gel in hypogonadal men," J Clin Endocrinol Metab. (2000) Dec;85(12):4500-10 (previously cited in IDS filed 11/12/2010(1))
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	104.	Noveon Product Specification: Carbopol ETD 2691 Polymer (November 2001)
	105.	Howell et al., "Testosterone Deficiency and Replacement," Horm Res, 56 Suppl 1: 86-92 (2001); Abstract
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	111.	Noveon TDS-207: Carbopol ETD Polymers: Formulation Tips (January 2002)
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	130.	Noveon Product Specification: Carbopol 934 NF Polymer (January 2003)
	131.	Noveon Product Specification: Carbopol 940 NF Polymer (January 2003)
	132.	Noveon Product Specification: Carbopol 941 NF Polymer (January 2003)
	133.	Noveon Product Specification: Carbopol 971P NF Polymer (January 2003)

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Application Number	10/829,618
Filing Date	4/20/2004
Inventor(s)	Dudley et al.
Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

Exam. Initial.	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	134.	Noveon Product Specification: Carbopol 974P NF Polymer (January 2003)
	135.	Noveon Product Specification: Carbopol 1342 NF (January 2003)
	136.	Noveon TDS-297: Carbopol Ultrez 21 Polymer, Technical Data Sheet (February 2003)
	137.	Noveon Product Specification: Carbopol Ultrez 10 NF Polymer (May 2003)
	138.	Greider, "Experts Divided on Value of Testosterone Therapy for Men," AARP Bulletin Online (July-August 2003)
	139.	Noveon Product Specification: Carbopol EZ-2 Polymer (August 2003)
	140.	Noveon Product Specification: Carbopol EZ-3 Polymer (August 2003)
	141.	Noveon Product Specification: Carbopol Ultrez 21 Polymer (September 2003)
	142.	Press Release, "The Endocrine Society Responds to the Institute of Medicine Report on Testosterone Therapy for Older Men" (November 17, 2003)
	143.	Basaria et al., "New Modalities of Transdermal Testosterone Replacement," Treat Endocrinol, 2(1): 1-9 (2003); Abstract
	144.	Hameed, A. et al. Delivery of testosterone replacement therapy. Curr Opin in Invest Drugs 2003. 4(1):1213-1219 (previously cited in IDS filed 11/12/2010(2))
	145.	Handbook of Pharmaceuticals Excipients, Fourth Edition, pp. 89-92, 95-100, 289-296, 309-313, 543-545, 566-567, 654-656, 691-693 (2003)
	146.	Rhoden et al., "Risks of Testosterone-Replacement Therapy and Recommendations for Monitoring," N Engl J Med 350:5, 482-492 (2004)
	147.	Testosterone and Aging: Clinical Research Directions, Institute of Medicine of the National Academies (Liverman and Blazer, eds.)(2004)

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Attorney Docket Number	003168.1043

Exam. Initial.	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	148.	Chan, TC. Percutaneous penetration enhancers: An update. Procdgs of 9th Biennial Intl Conf of Perspectives in Percutaneous Penetration, La Grand Motte, France, April 13, 2004; published January 2005 (previously cited in IDS filed 11/12/2010(2))
	149.	Press Release, Cellegy Announces Settlement of PDI Litigation (April 12, 2005)
	150.	Androgen Deficiency in Aging Men Questionnaire, Saint Louis University, available at <a href="http://www.slu.edu/adam">www.slu.edu/adam</a> (retrieved 5/23/2005)
	151.	Medline Plus, Drug Information: Testosterone Topical, available at <a href="http://www.nlm.nih.gov/medlineplus/druginfo/medmaster/a605020.html">www.nlm.nih.gov/medlineplus/druginfo/medmaster/a605020.html</a> (retrieved 6/3/2005)
	152.	Random House Webster's Unabridged Dictionary, 2d Edition, "pharmaceutical": p. 1451 and "drug": p. 600 (2005)
	153.	Random House Webster's Unabridged Dictionary, 2d Edition, "ethanol": p. 665 and "alcohol": p. 49 (2005)

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Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

**LITIGATION DOCUMENTS**

**Unimed Pharmaceuticals, Inc. v. Watson Pharmaceuticals, Inc., Docket No. 1:03-cv-02501-TWT (N.D. Ga. 2003)**

Exam. Initial.	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	154.	Docket Report for Unimed Pharmaceuticals, Inc. v. Watson Pharmaceuticals, Inc. (retrieved from PACER 1/4/2011)
	155.	Complaint by Unimed Pharmaceuticals filed 8/21/2003
	156.	Plaintiff Unimed Pharmaceutical, Inc.'s Rule 7.1 Corporate Ownership Disclosure Statement filed 8/21/2003
	157.	First Amended Complaint by Unimed Pharmaceuticals filed 8/22/2003
	158.	Answer and Counterclaim by Watson Pharmaceuticals filed 10/27/2003
	159.	Answer to Counterclaim by Unimed Pharmaceuticals filed 11/17/2003
	160.	Joint Preliminary Report and Discovery Plan filed 11/26/2003
	161.	Certificate of Interested Persons filed 11/26/2003
	162.	Letter by Watson Pharmaceuticals directed to Judge Thrash as a Response to the Letter Motion to Compel filed 10/21/2004
	163.	Watson Pharmaceutical's Motion to Issue Letter of Request for International Judicial Assistance dated 12/2/2004
	164.	Request for International Judicial Assistance by Judge Thrash dated 12/22/2004
	165.	Unimed Pharmaceuticals, Inc.'s Objections to Watson Pharmaceuticals, Inc.'s Notice of Depositions filed 3/17/2005
	166.	Watson's Principal Claim Construction Brief filed 7/25/2005

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Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

Exam. Initial.	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	167.	Plaintiff's Memorandum on Claim Construction (Redacted Version) filed 7/25/2005
	168.	Watson's Reply to Plaintiff's Principal Claim-Construction Brief dated 8/12/2005
	169.	Plaintiff's Opposition Brief on Claim Construction (Redacted Version) dated 8/12/2005
	170.	Watson's Motion to Strike Section VI of Plaintiffs' Memorandum on Claim Construction filed 8/12/2005
	171.	Plaintiff's Response to Watson's Motion to Strike Section VI of Plaintiff's Claim Construction Memorandum filed 8/26/2005
	172.	Watson's Reply in Support of Its Motion to Strike Section VI of Plaintiffs' Claim-Construction Memorandum filed 9/9/2005
	173.	Defendant Watson Pharmaceuticals, Inc.'s Motion for Partial Summary Judgment filed 9/9/2005
	174.	Plaintiffs' Consolidated Memorandum of Law in Opposition to Defendants' Motions for Partial Summary Judgment filed 10/17/2005
	175.	Unimed Pharmaceuticals, Inc.'s Statement of Additional Facts which are Material and Present A Genuine Issue for Trial filed 10/17/2005
	176.	Plaintiffs' Consolidated Response to Defendants Watson's and Paddock's Statement of Material Facts as to Which There are No Genuine Issues to be Tried filed 10/17/2005
	177.	Watson's Response to Plaintiffs' Statement of Additional Facts which are Material and Present a Genuine Issue for Trial filed 11/11/2005
	178.	Watson's Reply to Plaintiffs' Consolidated Opposition to Defendants' Motions for Partial Summary Judgment filed 11/11/2005

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Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

Exam. Initial.	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	179.	Defendant Watson Pharmaceuticals, Inc.'s Motion for Partial Summary Judgment of Invalidity of Claims 1-30 for Failure to Comply with the Written Description Requirement filed 11/23/2005
	180.	Plaintiffs' Consolidated Memorandum of Law in Opposition to Defendants' Motions for Partial Summary Judgment of Invalidity of Claims 1-30 filed 12/19/2005
	181.	Unimed Pharmaceuticals, Inc.'s Statement of Additional Facts which are Material and Present a Genuine Issue for Trial filed 12/19/2005
	182.	Plaintiffs' Consolidated Response to Defendants Watson's and Paddock's Statements of Material Facts as to Which There are No Genuine Issues to be Tried Regarding Invalidity of Claims 1-30 of the '894 Patent Lacking a Written Description under 35 U.S.C. § 112 filed 12/19/2005
	183.	Watson's Reply Memorandum of Law in Support of its Motion for Partial Summary Judgment of Invalidity of Claims 1-30 for Failure to Comply with the Written Description Requirement filed 1/19/2006
	184.	Watson's Response to Plaintiff's Statement of Additional Facts which are Material and Present a Genuine Issue for Trial filed 1/19/2006

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Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

**LITIGATION DOCUMENTS****Unimed Pharmaceuticals, Inc. v. Paddock Laboratories, Inc., Docket No. 1:03-cv-02503-TWT (N.D. Ga. 2003)**

Exam. Initial.	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	185.	Docket Report for Unimed Pharmaceuticals, Inc. v. Paddock Laboratories, Inc. (retrieved from PACER 1/4/2011)
	186.	Complaint by Unimed Pharmaceuticals dated 8/21/2003
	187.	Plaintiff Unimed Pharmaceuticals, Inc.'s Rule 7.1 Corporate Ownership Disclosure Statement filed 8/21/2003
	188.	First Amended Complaint by Unimed Pharmaceuticals filed 8/22/2003
	189.	Answer and Counterclaim by Paddock Laboratories filed 10/22/2003
	190.	Answer to Counterclaims by Unimed Pharmaceuticals filed 11/12/2003
	191.	Certificate of Interested Persons filed 11/21/2003
	192.	Joint Preliminary Report and Discovery Plan filed 11/21/2003
	193.	Defendant's Rule 26 Disclosures filed 12/12/2003
	194.	Paddock's Motion to Issue Letters of Request for International Judicial Assistance filed 12/1/2004
	195.	Request for International Judicial Assistance by Judge Thrash dated 12/9/2004
	196.	Unimed Pharmaceuticals, Inc.'s Objections to Paddock Laboratories, Inc.'s Notices of Depositions Under Rule 30(b)(6) dated 3/17/2005
	197.	Paddock's Opening Claim Construction Brief (Redacted Version) filed 7/25/2005

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Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

Exam. Initial.	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	198.	Paddock's Opposition Claim Construction Brief filed 8/12/2005
	199.	Defendant Paddock Laboratories, Inc.'s Motion for Partial Summary Judgment filed 9/27/2005
	200.	Memorandum in Support of Paddock's Motion for Partial Summary Judgment of Invalidity of Claims 1-30 of the '894 Patent as Lacking a Written Description as Required by 35 U.S.C. § 112, First Paragraph with Respect to the Claimed Ranges of Sodium Hydroxide filed 10/18/2005
	201.	Paddock's Reply Memorandum in Further Support of its Motion for Partial Summary Judgment as to the Inapplicability and Invalidity of the Certificate of Correction filed 11/11/2005
	202.	Paddock's Response to Plaintiffs' Statement of Additional Facts which are Material and Present a Genuine Issue for Trial filed 11/11/2005
	203.	Defendant Paddock Laboratories, Inc.'s Motion in Limine to Exclude Unimed's Argument and Expert Testimony on the Basis of, and Support in the Specification for, the Sodium Hydroxide Ranges Recited in Certain Claims of the '894 Patent filed 11/28/2005
	204.	Plaintiffs' Memorandum of Law in Opposition to Paddock's Motion in Limine to Exclude Plaintiffs' Argument and Expert Testimony on the Sodium Hydroxide Ranges filed 1/13/2006
	205.	Paddock's Reply memorandum in Further Support of its Motion for Partial Summary Judgment as to the Invalidity of Claims 1-30 under 35 U.S.C. § 112 filed 1/19/2006
	206.	Paddock's Response to Unimed's Statement of Additional Facts which are Material and Present a Genuine Issue for Trial with Respect to Paddock's motion of Summary Judgment that Claims 1-30 of the '894 Patent are Invalid under 35 U.S.C. § 112 filed 1/19/2006
	207.	Paddock's Reply Brief in Further Support of its Motion In Limine to Exclude

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Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

Exam. Initial.	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
		Unimed's Argument and Expert Testimony on the Basis of, and Support in the Specification for, the Sodium Hydroxide Ranges Recited in Certain Claims of the '894 Patent filed 1/31/2006
	208.	Consent Judgment and Order of Permanent Injunction dated 9/15/2006

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Application Number	10/829,618
Filing Date	4/20/2004
Inventor(s)	Dudley et al.
Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

**LITIGATION DOCUMENTS - In Re Androgel Antitrust Litigation (No. II), Docket No. 1:09-md-02084-TWT (N.D. Ga. 2009)**

Exam. Initial.	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	209.	Docket Report for In re Androgel Antitrust Litigation (No. II) (retrieved from PACER 1/5/2011)
	210.	Complaint, Meijer, Inc. v. Unimed Pharmaceuticals, Inc. (originally filed in C.D. Cal. on 2/2/2009)
	211.	Complaint, Louisiana Wholesale Drug Co. v. Unimed Pharmaceuticals, Inc. (originally filed in C.D. Cal. on 2/3/2009)
	212.	Complaint, Rochester Drug Co-operative, Inc. v. Unimed Pharmaceuticals, Inc. (originally filed in C.D. Cal. on 2/3/2009)
	213.	First Amended Complaint, Federal Trade Commission v. Watson Pharmaceuticals, Inc., Case No. CV 09-598 MRP (originally filed in C.D. Cal. on 2/12/2009)
	214.	Complaint, Stephen L. LaFrance Pharmacy, Inc. v. Unimed Pharmaceuticals, Inc. (originally filed in D.N.J. on 3/31/2009)
	215.	Complaint, Fraternal Order of Police v. Unimed Pharmaceuticals, Inc. (originally filed in D.N.J. on 4/17/2009)
	216.	Complaint, Scurto v. Unimed Pharmaceuticals, Inc. (originally filed in D.N.J. on 4/21/2009)
	217.	Complaint, United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund v. Unimed Pharmaceuticals, Inc. (originally filed in D. Minn. 2009)
	218.	Complaint, Rite Aid Corp. v. Unimed Pharmaceuticals, Inc. (originally filed in M.D. Penn. on 6/17/2009)
	219.	Complaint, Walgreen Co. v. Unimed Pharmaceuticals, Inc. (originally filed in M.D.

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		Penn. on 6/29/2009)
	220.	Complaint, Jabo's Pharmacy, Inc. v. Solvay Pharmaceuticals, Inc. (originally filed in Circuit Court for Cocke County, Tennessee on 10/30/2009)
	221.	Complaint, Supervalu Inc. v. Unimed Pharmaceuticals, Inc. (originally filed in N.D. Ga. on 4/7/2010)
	222.	Complaint, LeGrand v. Unimed Pharmaceuticals, Inc. (originally filed in N.D. Ga. on 9/10/2010)
	223.	Order Granting in Part and Denying in Part Defendant's Motions to Dismiss dated 2/22/2010
	224.	Amended Class Action Complaint and Jury Demand, Fraternal Order of Police v. Unimed Pharmaceuticals, Inc., Case No. 09-md-2084-TWT (filed 3/5/2010)

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